IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NEVRO CORP.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 19-325 (CFC)
	)	
STIMWAVE TECHNOLOGIES, INC.,	)	
	)	
Defendant.	)	

DECLARATION OF BEN PLESS IN SUPPORT OF
NEVRO'S MOTION FOR PRELIMINARY INJUNCTION

I, Ben Pless, declare as follows:

1. I have been retained to testify as an expert on behalf of Nevro Corp. ("Nevro") in the above-captioned case. I submit this declaration in support of Nevro's Motion for Preliminary Injunction. I have personal knowledge of the matters set forth in this declaration and, if called to testify as a witness, could and would do so competently.

I. BACKGROUND AND QUALIFICATIONS

2. I have over 30 years of experience developing and bringing to market medical devices in the fields of neuromodulation and electrical stimulation. A copy of my *curriculum vitae* is attached as **Exhibit A**.

3. I graduated in 1980 from the Massachusetts Institute of Technology ("MIT") with a degree in electrical engineering.

4. Following my graduation from MIT, I was employed as a design engineer at Intermedics from 1980-1984. I developed integrated circuits and other designs for implantable pacemaker systems.

5. I did additional coursework at Rice University as a PhD candidate from 1984 to 1985. I completed the coursework and passed the qualifying exam, but I left the PhD program prior to completing my thesis in order to start a new company called Ventritex.

6. I was a founder of Ventritex in 1985 and served as its Vice President of Product Development. I led the team that developed the first modern implantable cardiac defibrillator, innovating in areas including stored electrograms and biphasic waveforms.

7. In 1997, I joined St. Jude Medical as Vice President of Research and Development. I supervised approximately 300 employees and led the global pacemaker and defibrillator product development operations of the company.

8. I left St. Jude in 2000 to help start NeuroPace, which was focused at the time on developing a neurostimulator to treat epilepsy. I ultimately served as the CTO and COO of the company. I led the team that developed the first chronic implantable device that senses and analyzes electrocorticographic information from the brain in order to automatically deliver responsive therapy.

9. In 2007, I founded Autonomic Technologies and served as the President and CEO of the company until 2015. I led the development of the first trans-oral permanently implantable neurostimulator for the treatment of headaches.

10. Since 2016, I have served as an Executive in Resident at Partners HealthCare Innovation. I assist clinicians with translating clinical observations to inventions, intellectual property, and new startup companies.

11. Since 2018, I have also served as an Executive Director at Cala Health, leading efforts to develop respiration-gated neurostimulation as a therapy for a range of indications. I previously served on the Scientific Advisory Board of Cala Health from 2014 through 2018.

12. I also provide consulting services to the medical device community through Pivotal Design Labs.

13. I have served on several boards as detailed in my CV. For instance, I helped found Neurotechnology Innovations Translator ("NIT"), which focuses on developing and commercializing pioneering neurotechnology solutions to improve patient well-being.

14. I have been awarded more than 150 patents by the United States Patent & Trademark Office for my inventions.

15. My opinions concerning this matter are my own and do not represent those of any organization with which I am affiliated.

16. I am being compensated for my time on this matter at my standard hourly rate of $800 per hour. My compensation is not contingent upon the opinions I offer or the outcome of the matter.

17. I have served as an expert witness in the case of *Nevro Corp. v. Boston Scientific Corporation et al.*, Case No. 3-16-cv-06830-VC-MEJ in the Northern District of California, and have also been compensated for my time on that matter.

II. BASIS FOR OPINIONS

18. In forming my opinions, I have reviewed and considered U.S. Patent Nos. 9,327,127 ("the '127 patent") and 8,874,222 ("the '222 patent") and their file histories, documents regarding Stimwave's spinal cord stimulation therapy and products, and other documents referenced in this declaration. These materials are identified more fully in the list attached as **Exhibit B**.

19. My opinions are also based on my education, knowledge, and experience in science and engineering, particularly in the fields of neuromodulation and electrical stimulation medical devices.

III. SUMMARY OF OPINIONS

20. I understand that Nevro is seeking a preliminary injunction against Stimwave based on the ’127 and ’222 patents. In connection with these proceedings, counsel for Nevro has asked that I provide my opinions regarding whether Stimwave infringes claims 22 and 23 of the ’127 patent and claims 24, 28, and 48 of the ’222 patent.

21. Based on my analysis of the information currently available to me, it is my opinion that Stimwave infringes claims 22 and 23 of the ’127 patent and claims 23, 24, and 48 of the ’222 patent.

22. I understand that Nevro is seeking discovery and information from Stimwave regarding its SCS therapy and products, and that additional information from Stimwave may become available to me before the preliminary injunction proceedings are complete. I reserve the right to supplement or amend my opinions in view of any additional information.

IV. OVERVIEW OF SPINAL CORD STIMULATION (SCS) THERAPY

23. SCS therapy is a type of neuromodulation that uses electrical pulses to stimulate neurons in the spinal cord region. The electrical pulses are generated by a signal generator and are delivered to the spinal cord via implantable leads—insulated wires with electrodes that transmit the electrical pulses.

24. An early form of spinal cord stimulation (subdural dorsal column stimulation) was first used to treat pain in 1967 by Norman Sheeley. Koki Shimoji and his colleagues reported the first use of epidural spinal cord stimulation in 1971. In 1976, Cordis Corporation produced the first fully implantable commercial spinal cord stimulator. SCS therapy was approved by the Food and Drug Administration (FDA) in 1989 to relieve pain from nerve damage in the trunk, arms, or legs (neuropathic pain). Currently, approximately 35,000 patients undergo spinal cord stimulator implants worldwide each year.

25. Since its advent, traditional SCS therapy employs electrical signals generated at low frequencies, often under 100 Hz, and works by generating the sensation of "paresthesia" mapped over the area of pain. Paresthesia is an abnormal sensation that can be generated by the application of electrical signals and can be perceived by the patient as, e.g., tingling, numbness, or pins-and-needles sensation. The leads are purposefully placed and adjusted in locations in the epidural space along the spinal cord so that the generated paresthesia sensation overlaps with the area of pain to mask the feeling of pain. During the lead implantation procedure, the patient is partially woken to participate in "paresthesia mapping" by reporting to the physician where the paresthesias are felt when the physician turns on electrical stimulation for different electrodes and adjusts the leads. The goal is to get complete coverage of the patient's area of pain with the sensation of paresthesias caused by electrical stimulation.

26. In addition to the signal generator and the leads, SCS systems typically include a device known as a programmer or clinician programmer. A clinical representative or physician may use the programmer to program the signal generator—that is, to select specified signal parameters such as the frequency, amplitude, and pulse width of the electrical pulses. The system may also include a remote control that allows the patient to turn the stimulation on and off and may also allow the patient to vary the intensity of the stimulation within the parameters selected by the clinical representative or physician.

27. In traditional SCS therapy, selecting the electrodes that provide the best paresthesia coverage over the areas of pain is one of the most important programming settings. These electrodes are identified during the "paresthesia mapping" with the patient reporting to the physician where the paresthesias are felt. Once the paresthesia coverage is optimized, the frequency of the stimulating pulses is adjusted to achieve strong paresthesia sensations that are

comfortable for the patient. Frequencies such as 20 Hz might be perceived as thumping, while frequencies such as 80 Hz might be felt as smoother paresthesias. In general, better paresthesia coverage is achieved with the selection of wider pulse widths (around 500 μs). However, to reduce energy consumption and to get the longest battery life, the lowest frequency and narrowest pulse width may be used, consistent with satisfactory pain relief.

28. The perception of pain occurs in the brain and is a complex phenomenon. SCS modifies the pain signals going to the brain in such a way that less pain is perceived. How traditional SCS therapy works to control chronic neuropathic pain is not completely understood. It is likely that, to some extent, paresthesia sensations interfere with the perception of chronic pain much like rubbing a sore part of the body reduces the feeling of soreness (this is known as the "gate theory" of pain control). However, scientific studies have shown that this is probably not the whole story. What is clear is that SCS therapy does not simply block neurons. This is evident because, while chronic neuropathic pain is suppressed by SCS therapy, regular sensations (like touch) and acute nociceptive pain (like hitting a finger with a hammer) are largely unaffected by SCS.

29. For several decades, innovation in spinal cord stimulators was largely a result of improving the technology used to perform traditional SCS therapy, not of improving the SCS therapy itself. For example, the first implantable spinal cord stimulators of the 1970s had no batteries and were radiofrequency powered by an external unit that the patient had to carry whenever they wanted to use the implanted device. While the technology was crude by today's standards, the basic therapy was the same as traditional SCS today, i.e., comparatively low frequency pulses (from 20 to 120 Hz) delivered to locations of the patient's spinal cord to produce paresthesias that overlap with areas where the patient feels chronic pain. Technologies

improved over the years to make devices smaller, entirely implanted, more reliable, and more programmable, but the therapeutic strategy was unchanged.

30. Because of the lack of innovation in SCS therapy, it was not responsive to the clinical need for improvement. Many issues plagued traditional SCS that were not addressed by the technology improvements. For example, the need to have patients provide feedback during surgery about where they feel paresthesias (paresthesia mapping) is time consuming and can be distressing for the patient. In addition, the majority of patients do not like the sensation of paresthesia that traditional SCS depends on to achieve pain relief. Largely, patients will put up with paresthesia as a lesser evil to achieve pain relief, but some patients find the paresthesia intolerable. The sensation of the paresthesia can also morph over time and can change dramatically with body position, going suddenly from comfortable to shocking or painful. Patients have to constantly use their remote controls to change programmed settings to deal with inconsistent therapy.

31. Nevro changed all that by introducing technology that innovated over the traditional SCS therapeutic strategy in ways that provide important benefits to the patient and to the physician. Nevro's therapy provides superior pain relief over traditional SCS therapy without relying on paresthesia.

32. Rather than using low frequency signals to generate paresthesia as in traditional SCS therapy, Nevro's innovation provides high frequency and/or paresthesia-free SCS, as described in Nevro's patents. With the Nevro therapy, the leads are placed based on anatomical landmarks (such as vertebral levels T8 – T12) rather than locations mapped to paresthesia, so the patients do not need to provide feedback during the implantation procedure. This makes the implant procedure faster and less stressful. Further, because there is no paresthesia, no

monitoring of the paresthesia sensations is necessary to select the stimulation parameters. Also, because the Nevro therapy is paresthesia-free, patient tolerability of the therapy is much better. Nevro's therapy is robust and accommodates body motion and position, resulting not only in better pain relief but also improved quality of life for the patients. In contrast to patients using traditional SCS, patients using the Nevro therapy do not have to constantly use their remote control to change programming settings to deal with inconsistent therapy. After decades of traditional SCS therapy, the Nevro therapy has been a true breakthrough that has provided many patients with pain relief that would otherwise not be possible.

V. NEVRO'S HIGH-FREQUENCY, PARESTHESIA-FREE THERAPY HAD TO OVERCOME WIDESPREAD SKEPTICISM IN THE INDUSTRY

33. I recall first hearing of Nevro's work around 2010 to 2011. When Nevro would go to the annual meeting of the North American Neuromodulation Society ("NANS")—the largest organization in the United States of professionals involved in the field of neuromodulation—people paid attention because Nevro's therapy was so different from the low frequency, paresthesia-based therapy provided by the existing SCS treatments at the time.

34. In 2012, I was a Scientific Chair on what is known as the I3 at NANS. I3 stands for Invention, Investment, and Invigoration. In that position, I participated in the governance of NANS and interacted with people in the highest level at the organization. I remember very well the skepticism that was expressed regarding paresthesia-free high frequency therapy and whether it was scientifically sound. I shared it, and initially did not believe that the therapy could work.

35. People were highly skeptical that increasing the frequency to 10,000 Hz would provide any additional benefit that would be of interest. As one 2007 article on spinal cord stimulation stated:

> The most common way to increase the intensity of the stimulus is to increase its amplitude (i.e., current, voltage). For a given

> amplitude the intensity of the stimulus can also be increased by augmenting the duration of the pulse. *However, there is no physiological evidence that increasing the pulse rate beyond physiological limits (~300 pps) will provide therapeutic benefit* as neural transmission may become blocked either by inactivation of sodium channels (depolarization block) or presynaptic neurotransmitter depletion.[1] (emphasis added).

36. While increasing the frequency to 10,000 Hz was not perceived to be of any benefit, many questioned whether stimulation delivered to the spinal cord at that frequency could be safe given that the frequency was so much higher than the frequencies that were typically used in SCS therapy, which were more than a hundred times smaller. Many believed that high-frequency signals created a transmission "block" on nerves and that applying such high-frequency "block" signals to the spinal cord region could destroy spinal cord tissue and/or interfere with a patient's motor functions.

37. Because of the lack of paresthesia, the SCS industry was highly skeptical of Nevro's claims that its high-frequency and/or paresthesia-free spinal cord stimulation therapy would provide any pain relief. For decades, traditional SCS therapy relied on paresthesia to overlap a patient's area of pain, and advances in the SCS field had focused on improving the accuracy of paresthesia mapping.

VI. NEVRO'S PATENTS

38. The '127 and '222 patents belong to the same patent family and cover Nevro's groundbreaking spinal cord stimulation therapy. Each of these patents is titled "Selective High Frequency Spinal Cord Modulation for Inhibiting Pain with Reduced Side Effects, and Associated Systems and Methods." The '127 and '222 patents share a common specification. The '127 patent issued on May 3, 2016. The '222 patent issued on October 28, 2014.

[1] Ex. 4, Foletti et al, "Neurostimulation Technology for the Treatment of Chronic Pain: A Focus on Spinal Cord Stimulation," *Expert Rev. Med. Devices* 4(2) at 202 (2007).

39. The ’127 and ’222 patents each claim priority to two provisional applications, Provisional App. No. 61/176,868 filed on May 8, 2009 and Provisional App. No. 61,171,790 filed on April 22, 2009. The ’127 and ’222 patents also each claim priority to U.S. Patent App. No. 12/765,747, filed on April 22, 2010.

40. Both the ’127 and ’222 patents are method patents. The ’127 patent claims are generally directed to methods for treating a patient with high frequency, paresthesia-free therapy. The ’222 patent claims are generally directed to methods for configuring SCS systems by programming them to provide high frequency, paresthesia-free therapy.

41. For the preliminary injunction proceedings, I understand that the five claims at issue are claims 22 and 23 of the ’127 patent and claims 24, 28, and 48 of the ’222 patent. These claims, along with the independent claims from which they depend, are reproduced below.

’127 patent claim 22	1. A method for treating a patient, comprising: delivering an electrical signal to the patient’s spinal cord via at least one implantable signal delivery device; and wherein the electrical signal has a frequency of from 1.5 kHz to 50 kHz and does not create paresthesia in the patient. 22. The method of claim 1 wherein the electrical signal has a frequency of from 3 kHz to 10 kHz.
’127 patent claim 23	1. A method for treating a patient, comprising: delivering an electrical signal to the patient’s spinal cord via at least one implantable signal delivery device; and wherein the electrical signal has a frequency of from 1.5 kHz to 50 kHz and does not create paresthesia in the patient. 23. The method of claim 1 wherein the electrical signal has a frequency of 10 kHz.

’222 patent claim 24	23. A method for configuring a signal generator to deliver a therapy signal to a patient’s spinal cord, the method comprising: programming the signal generator to (1) generate a non-paresthesia-producing therapy signal, wherein at least a portion of the therapy signal has a frequency in a frequency range of from 1.5 kHz to 100 kHz; and (2) deliver the therapy signal to the patient’s spinal cord via a signal delivery device implanted in the patient’s epidural space. 24. The method of claim 23, wherein the frequency is 10 kHz.
’222 patent claim 28	23. A method for configuring a signal generator to deliver a therapy signal to a patient’s spinal cord, the method comprising: programming the signal generator to (1) generate a non-paresthesia-producing therapy signal, wherein at least a portion of the therapy signal has a frequency in a frequency range of from 1.5 kHz to 100 kHz; and (2) deliver the therapy signal to the patient’s spinal cord via a signal delivery device implanted in the patient’s epidural space. 28. The method of claim 23 wherein the frequency range is from 3 kHz to 10 kHz.
’222 patent claim 48	45. A method for configuring a signal generator to deliver a therapy signal to a patient’s spinal cord via an implantable signal delivery device, wherein the implantable signal delivery device is implantable in the patient’s epidural space, the method comprising: programming the signal generator to generate and deliver a therapy signal to the patient’s spinal cord, via the implantable signal delivery device, wherein at least a portion of the therapy signal has a frequency in a frequency range of from about 1.5 kHz to about 50 kHz, a current amplitude in an amplitude range of from about 0.1 mA to about 6 mA, a pulse width between about 10 microseconds and about 333 microseconds, and at least partially reduces the patient’s sensation of pain without generating paresthesia. 48. The method of claim 45, wherein the frequency range is from about 3 kHz to about 20 kHz and the pulse width is between about 25 microseconds and about 166 microseconds.

42. The claims of the ’127 and ’222 patents are similar to the claims of another related Nevro patent from the same patent family, U.S. Patent No. 8,359,102 (“the ’102 patent”). The ’102 patent was challenged in two *inter partes review* petitions filed by Boston Scientific

seeking to invalidate the claims in proceedings before the Patent Trial and Appeal Board ("PTAB"). Both petitions were denied. The PTAB declined to institute proceedings and found that the petitions had not shown a reasonable likelihood of prevailing on the assertion that the claims were invalid. (Exs. 32-33, 1203 IPR Decision at 20, 1204 IPR Decision at 14.)

VII. NEVRO'S SENZA® SYSTEM AND HF10® THERAPY

43. Nevro's SCS system is called the Senza system. Its high frequency, paresthesia-free therapy is called HF10 therapy. Nevro's Senza system and HF10 therapy practice the inventions claimed by Nevro's patents, including the '127 and '222 patents. Indeed these inventions go to the core of Nevro's differentiating high frequency, paresthesia-free technology.

44. The Senza system includes a signal generator, implantable leads, a clinician programmer, and a patient remote control. (Ex. 59, Nevro Physician Implant Manual at 5.) The Senza system has a frequency range of 2 Hz to 10,000 Hz. (Ex. 58, Nevro Patient Manual at 41.) The leads are implanted in the patient's epidural space in the spinal cord. (Ex. 59, Physician Implant Manual at 6.)

45. Nevro's clinical representatives use the clinician programmer to program the Senza system to deliver Nevro's HF10 therapy, which has a frequency of 10 kHz, and typically has a pulse width of 30 microseconds (μs), and an amplitude of 1 to 5 mA. (Ex. 2, Kapural SENZA RCT at 852.) HF10 therapy does not produce paresthesia. (*Id.* at 851, 855.)

VIII. STIMWAVE'S SCS THERAPY

46. Stimwave is a medical device company that markets the Freedom SCS systems, including the Freedom-4A and the Freedom-8A. Until recently, Stimwave's FDA approval was only for systems with stimulation frequencies limited to the range of 5 Hz to 1500 Hz.

47. On April 1, 2019, Stimwave announced it had received FDA clearance for waveforms up to 10 kHz. (Ex. 9, April 1, 2019 Stimwave Press Release.) Its press release refers

to "FDA cleared waveforms to 10,000 Hz available commercially in USA providing the most versatile opioid free neurostimulation options in the industry." (*Id.*)

48. Stimwave's SCS systems do not have an implantable battery, which Stimwave markets as an innovative and beneficial feature. Its press release announcing its FDA approval for 10 kHz SCS claims that its study results "showed true paradigm shifting outcomes for the battery-free, opioid free, pain management system." (*Id.*)

49. As I discussed above, however, implantable spinal cord stimulators having no batteries are old technology that dates back to the 1970s. The lack of an implantable battery was considered a drawback because patients had to carry the external power source whenever they wanted to use the therapy. These systems also make it more difficult for patients to receive therapy while performing activities or while sleeping. The development of implantable battery technology was an innovation that made SCS systems more reliable and convenient for patients.

50. In any event, the lack of an implantable battery in Stimwave's SCS systems does not affect the infringement analysis I present below. The patent claims that I discuss here do not require an implantable battery.

IX. LEGAL STANDARDS

51. I have not been asked to offer an opinion on the law and I will not do so; however, as an expert assisting the Court in determining infringement, I understand that I am obliged to follow existing law. I am informed of several principles concerning patent infringement that I have used in arriving at my conclusions:

52. I understand that the patentee must show that it is more likely than not that the alleged infringer has infringed an asserted claim of a patent.

53. I understand that the determination of whether an accused product or method infringes a patent claim is a two-step process: (1) the claims of the patent must be construed to

determine their meaning; and (2) the properly construed claims must then be compared with the accused product or method.

54. I understand that infringement can be direct or indirect. As to method claims, I understand that direct infringement occurs where all steps of a claimed method are performed by or are attributable to a single party.

55. I understand that indirect infringement can occur through inducement. I understand that inducing infringement is intentionally causing another to directly infringe a patent. I understand that indirect infringement requires that someone has directly infringed the asserted patents. I understand that in order for an alleged infringer to have induced infringement, the alleged infringer must have induced another to directly infringe a claim of an asserted patent; if there is no direct infringement by anyone, there can be no induced infringement. I understand that, as with direct infringement, I must determine induced infringement on a claim-by-claim basis.

56. I understand that in order to establish induced infringement, the patent holder must show that the alleged infringer: (1) intentionally took action that actually induced direct infringement; (2) was aware of the patent; and (3) knew that the acts it caused would infringe the patent. The accused infringer may be considered to have known that the acts it was causing would infringe the patent if it subjectively believed there was a high probability that the direct infringer's product or method was infringing and nevertheless deliberately took steps to avoid learning that fact, in other words, that the inducing party "willfully blinded" itself to the infringing nature of the direct infringer's acts.

X. DIRECT INFRINGEMENT OF THE ’127 PATENT

57. Stimwave directly infringes claims 22 and 23 of the ’127 patent as set forth in my analysis below. Claims 22 and 23 are dependent claims that each depend from independent claim 1 of the ’127 patent. Therefore, my analysis below also includes claim 1.

A. ’127 Patent Claim 1

’127 patent claim 1	1. A method for treating a patient, comprising: delivering an electrical signal to the patient’s spinal cord via at least one implantable signal delivery device; and wherein the electrical signal has a frequency of from 1.5 kHz to 50 kHz and does not create paresthesia in the patient.

1. Claim 1, Preamble: “A method for treating a patient, comprising:”

58. The claim is directed to a method for treating a patient. Stimwave uses its SCS therapy to treat patients. Stimwave’s press release announcing the launch of its high frequency SCS included a statement from its CEO, Laura Tyler Perryman: “With the FDA clearance of 10,000 Hz, Stimwave U.S. patients now have an additional waveform to ensure maximum amount of ability to modify their programming to fit their individual pain management needs and decrease the effects of plasticity.” (Ex. 9, April 1, 2019 Stimwave Press Release.)

59. The Indications for Use for Stimwave’s Freedom Spinal Cord Stimulator (SCS) System also describes its use in treating patients: “The Freedom Spinal Cord Stimulator (SCS) System is intended as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach for chronic, intractable pain of the trunk and/or lower limbs, including unilateral or bilateral pain.” (Ex. 62, K182720 FDA Summary at Indications for Use.)

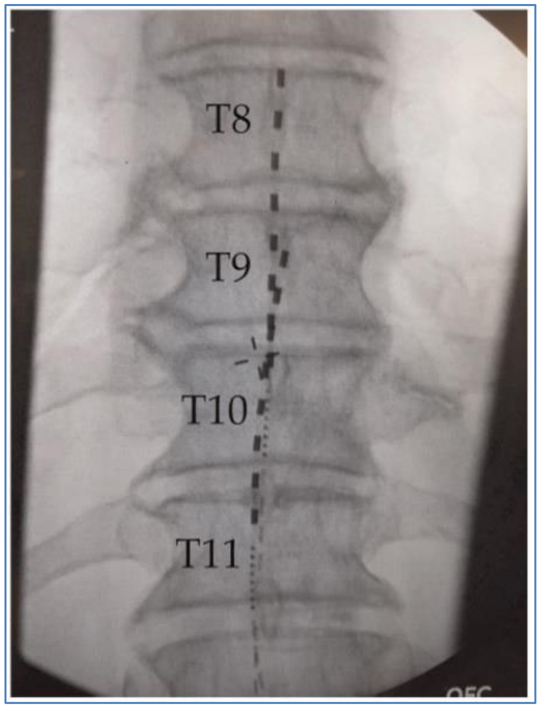
2. Claim 1, Element [a]: “delivering an electrical signal to the patient’s spinal cord via at least one implantable signal delivery device; and”

60. The claim provides that the therapy is delivered to the patient’s spinal cord via an implantable signal delivery device. As I explained above, in SCS systems these signal delivery

devices include leads, which are insulated wires with electrodes that deliver the electrical pulses to the spinal cord.

61. Stimwave's Freedom-4A and Freedom-8A include such signal delivery devices. Stimwave's product website states: "The stimulator has small metal electrodes near the tip that create an electrical field of energy when power is applied." (Ex. 17, Stimwave Freedom Stimulators website.) The images below from Stimwave's product website depict the signal delivery devices for the Freedom-4A and Freedom-8A. In these images, the electrodes are the shiny metal bands toward the left side of each device.

62. Stimwave's signal delivery devices are implantable. As explained in Stimwave's publication on its high frequency SCS study: "Subjects were implanted with two separate wireless stimulators positioned with the electrodes between the T8 and T11 vertebral levels regardless of the randomization assignment (Figure 2). All subjects were immediately implanted with a permanent wireless system using a Tuohy needle, placing the stimulator electrodes in the epidural space." (Ex. 18, Pain Medicine article at 2.) The image below from Stimwave's study publication depicts the implanted signal delivery devices.



63. Stimwave's clinical representatives program its SCS systems to deliver electrical signals to the patient's spinal cord via these signal delivery devices. Stimwave's user manual for its WaveCrest programmer states that only its trained clinical representatives may use the programmer. (Ex. 19, WaveCrest Programmer User Manual at 3.)

3. Claim 1, Element [b]: "wherein the electrical signal has a frequency of from 1.5 kHz to 50 kHz"

64. The claim recites that the electrical signal has a frequency of from 1.5 kHz to 50 kHz. Stimwave's high frequency SCS therapy is at a frequency of 10 kHz.

65. In Stimwave's press release announcing the launch of its high frequency SCS, its CEO stated: "With the FDA clearance of 10,000 Hz, Stimwave U.S. patients now have an additional waveform to ensure maximum amount of ability to modify their programming to fit their individual pain management needs and decrease the effects of plasticity." (Ex. 9, April 1, 2019 Stimwave Press Release.)

66. Stimwave's study publication also states that its high frequency SCS therapy is at a frequency of 10 kHz. The title specifically refers to "Wireless High-Frequency Spinal Cord Stimulation (10 kHz)," and the abstract explains that it used the "wireless Freedom Spinal Cord Stimulator (WSCS) System for the treatment of chronic back and/or leg pain associated with failed back surgery syndrome (FBSS) refractory to standard medical treatment utilizing 10-kHz stimulation (high-frequency [HF])." (Ex. 18, Pain Medicine article at 1.)

67. Since the FDA approval of Stimwave's high frequency SCS, a number of public postings on LinkedIn indicate that Stimwave patients are receiving treatment with Stimwave's 10 kHz SCS therapy. (Exs. 12-14, LinkedIn posts.)

4. Claim 1, Element [c]: "and does not create paresthesia in the patient."

68. The claim recites that the therapy does not create paresthesia in the patient. As I explained above, paresthesia refers to sensations such as tingling, numbness, or pins-and-needles that are used in traditional low frequency SCS to overlap with the patient's area of pain and mask the feeling of pain.

69. Stimwave's high frequency SCS does not create paresthesia in the patient. Stimwave's high frequency study publication states that "tonic stimulation generates paresthesia whereas HF [high frequency] stimulation does not." (Ex. 18, Pain Medicine article at 2.)

70. In addition, Stimwave's "How It Works" webpage for its Freedom system states that "[t]he stimulation can feel like a tingling sensation or no sensation at all." (Ex. 60, http://stimwave.com/mobile/patients/how-it-works/.) "[N]o sensation at all" indicates that the therapy does not create paresthesia in the patient.

B. '127 Patent Claim 22

'127 patent claim 22	22. The method of claim 1 wherein the electrical signal has a frequency of from 3 kHz to 10 kHz.

71. Claim 22 depends from claim 1 and specifies the further limitation "wherein the electrical signal has a frequency of from 3 kHz to 10 kHz."

72. As discussed above for claim 1, element [b], Stimwave's high frequency SCS therapy is at a frequency of 10 kHz. This falls within the range of 3 kHz to 10 kHz specified in claim 22. Based on Stimwave's public statements and Answer, it appears that Stimwave is also providing high frequency SCS therapy at other "frequencies up to 10,000 Hz." (Ex. 9, April 1, 2019 Stimwave Press Release; D.I. 8, ¶ 7.) To the extent that those frequencies are 3 kHz or higher, they also fall within the range specified in claim 22.

73. Therefore, Stimwave infringes claim 22.

C. '127 Patent Claim 23

'127 patent claim 23	23. The method of claim 1 wherein the electrical signal has a frequency of 10 kHz.

74. Claim 23 depends from claim 1 and specifies the further limitation "wherein the electrical signal has a frequency of 10 kHz."

75. As discussed above for claim 1, element [b], Stimwave's high frequency SCS therapy is at a frequency of 10 kHz. This satisfies the 10 kHz frequency specified in claim 23. Therefore, Stimwave infringes claim 23.

XI. DIRECT INFRINGEMENT OF THE '222 PATENT

76. Stimwave directly infringes claims 24, 28, and 48 of the '222 patent as set forth in my analysis below. Claims 24 and 28 are dependent claims that each depend from independent claim 23. Claim 48 depends from independent claim 45. Therefore, my analysis below also includes independent claims 23 and 45. I understand, however, that Nevro is not asserting either claim 23 or claim 45 in its preliminary injunction motion.

A. ’222 Patent Claim 23

’222 patent claim 23	23. A method for configuring a signal generator to deliver a therapy signal to a patient’s spinal cord, the method comprising: programming the signal generator to (1) generate a non-paresthesia-producing therapy signal, wherein at least a portion of the therapy signal has a frequency in a frequency range of from 1.5 kHz to 100 kHz; and (2) deliver the therapy signal to the patient’s spinal cord via a signal delivery device implanted in the patient’s epidural space.

1. Claim 23, Preamble: “A method for configuring a signal generator to deliver a therapy signal to a patient’s spinal cord, the method comprising:”

77. The claim is directed to a method of “configuring a signal generator to deliver a therapy signal to a patient’s spinal cord.” In the context of the claim, this language refers to “programming the signal generator” to generate and deliver a therapy signal to the patient’s spinal cord in accordance with certain parameters set forth in the rest of the claim. I analyze how Stimwave satisfies those elements in the sections below.

2. Claim 23, Element [a]: “programming the signal generator to”

78. The claim recites programming the signal generator to generate and deliver a therapy signal. As discussed above, a clinical representative or physician may use a programmer to select certain specified signal parameters for the therapy.

79. Stimwave’s clinical representatives program the signal generator in its SCS systems to deliver electrical signals to the patient’s spinal cord via Stimwave’s signal delivery devices. The programming is performed using Stimwave’s WaveCrest programmer. (Ex. 19, WaveCrest Programmer User Manual.) Stimwave’s user manual for its WaveCrest programmer states that only its trained clinical representatives may use the programmer. (*Id.* at 3.)

3. Claim 23, Element [b]: "(1) generate a non-paresthesia-producing therapy signal, wherein at least a portion of the therapy signal has a frequency in a frequency range of from 1.5 kHz to 100 kHz; and"

80. The claim recites a non-paresthesia-producing therapy signal. As I explained above, paresthesia refers to sensations such as tingling, numbness, or pins-and-needles that are used in traditional low frequency SCS to overlap with the patient's area of pain and mask the feeling of pain.

81. Stimwave's high frequency SCS therapy does not produce paresthesia. Stimwave's high frequency study publication states that "tonic stimulation generates paresthesia whereas HF [high frequency] stimulation does not." (Ex. 18, Pain Medicine article at 2.)

82. In addition, Stimwave's "How It Works" webpage for its Freedom system states that "[t]he stimulation can feel like a tingling sensation or no sensation at all." (Ex. 60, http://stimwave.com/mobile/patients/how-it-works/.) "[N]o sensation at all" indicates that the therapy does not produce paresthesia.

83. The claim recites that at least a portion of the therapy signal has a frequency is in a frequency range from 1.5 kHz to 100 kHz. Stimwave's high frequency SCS therapy is at a frequency of 10 kHz.

84. In Stimwave's press release announcing the launch of its high frequency SCS, its CEO stated: "With the FDA clearance of 10,000 Hz, Stimwave U.S. patients now have an additional waveform to ensure maximum amount of ability to modify their programming to fit their individual pain management needs and decrease the effects of plasticity." (Ex. 9, April 1, 2019 Stimwave Press Release.)

85. Stimwave's study publication also states that its high frequency SCS therapy is at a frequency of 10 kHz. The title specifically refers to "Wireless High-Frequency Spinal Cord Stimulation (10 kHz)," and the abstract explains that it used the "wireless Freedom Spinal Cord

Stimulator (WSCS) System for the treatment of chronic back and/or leg pain associated with failed back surgery syndrome (FBSS) refractory to standard medical treatment utilizing 10-kHz stimulation (high-frequency [HF]).” (Ex. 18, Pain Medicine article at 1.)

86. Since the FDA approval of Stimwave’s high frequency SCS, a number of public postings on LinkedIn indicate that Stimwave patients are receiving treatment with Stimwave’s 10 kHz SCS therapy. (Exs. 12-14, LinkedIn posts.)

4. Claim 23, Element [c]: “(2) deliver the therapy signal to the patient’s spinal cord via a signal delivery device implanted in the patient’s epidural space.”

87. The claim provides that the system is programmed to deliver the therapy signal to the patient’s spinal cord via a signal delivery device. As I explained above, in SCS systems these signal delivery devices include leads, which are insulated wires with electrodes that deliver the electrical pulses to the spinal cord.

88. Stimwave’s Freedom-4A and Freedom-8A include such signal delivery devices. Stimwave’s product website states: “The stimulator has small metal electrodes near the tip that create an electrical field of energy when power is applied.” (Ex. 17, Stimwave Freedom Stimulators website.) The images below from Stimwave’s product website depict the signal delivery devices for the Freedom-4A and Freedom-8A. In these images, the electrodes are the shiny metal bands toward the left side of each device.

89. The claim refers to a signal delivery device "implanted in the patient's epidural space." Stimwave's signal delivery devices are implanted in the patient's epidural space. As explained in Stimwave's publication on its high frequency SCS study: "Subjects were implanted with two separate wireless stimulators positioned with the electrodes between the T8 and T11 vertebral levels regardless of the randomization assignment (Figure 2). All subjects were immediately implanted with a permanent wireless system using a Tuohy needle, placing the stimulator electrodes in the epidural space." (Ex. 18, Pain Medicine article at 2.)

90. Stimwave's product website also states that its signal delivery devices are implanted in the epidural space: "The Freedom SCS (Spinal Cord Stimulator) System is used to treat pain with placement of electrodes in the epidural space of the spinal column." (Ex. 61, http://stimwave.com/mobile/products/.)

B. '222 Patent Claim 24

'222 patent claim 24	24. The method of claim 23, wherein the frequency is 10 kHz.

91. Claim 24 depends from claim 23 and specifies the further limitation "wherein the frequency is 10 kHz."

92. As discussed above for claim 23, element [b], Stimwave's high frequency SCS therapy is at a frequency of 10 kHz. This satisfies the 10 kHz frequency specified in claim 24. Therefore, Stimwave infringes claim 24.

C. ’222 Patent Claim 28

’222 patent claim 28	28. The method of claim 23 wherein the frequency range is from 3 kHz to 10 kHz.

93. Claim 28 depends from claim 23 and specifies the further limitation “wherein the frequency range is from 3 kHz to 10 kHz.”

94. As discussed above for claim 23, element [b], Stimwave’s high frequency SCS therapy is at a frequency of 10 kHz. This falls within the range of 3 kHz to 10 kHz specified in claim 28. Based on Stimwave’s public statements and Answer, it appears that Stimwave is also providing high frequency SCS therapy at other “frequencies up to 10,000 Hz.” (Ex. 9, April 1, 2019 Stimwave Press Release; D.I. 8, ¶ 7.) To the extent that those frequencies are 3 kHz or higher, they also fall within the range specified in claim 28.

95. Therefore, Stimwave infringes claim 28.

D. ’222 Patent Claim 45

’222 patent claim 45	45. A method for configuring a signal generator to deliver a therapy signal to a patient’s spinal cord via an implantable signal delivery device, wherein the implantable signal delivery device is implantable in the patient’s epidural space, the method comprising: programming the signal generator to generate and deliver a therapy signal to the patient’s spinal cord, via the implantable signal delivery device, wherein at least a portion of the therapy signal has a frequency in a frequency range of from about 1.5 kHz to about 50 kHz, a current amplitude in an amplitude range of from about 0.1 mA to about 6 mA, a pulse width between about 10 microseconds and about 333 microseconds, and at least partially reduces the patient’s sensation of pain without generating paresthesia.

1. Claim 45, Preamble: "A method for configuring a signal generator to deliver a therapy signal to a patient's spinal cord via an implantable signal delivery device, wherein the implantable signal delivery device is implantable in the patient's epidural space, the method comprising:"

96. The claim is directed to a method of "configuring a signal generator to deliver a therapy signal to a patient's spinal cord." In the context of the claim, this language refers to "programming the signal generator" to generate and deliver a therapy signal to the patient's spinal cord in accordance with certain parameters set forth in the rest of the claim. I analyze how Stimwave satisfies those elements in the sections below.

97. The claim provides that the system is programmed to deliver the therapy signal to the patient's spinal cord "via an implantable signal delivery device." As I explained above, in SCS systems these signal delivery devices include leads, which are insulated wires with electrodes that deliver the electrical pulses to the spinal cord.

98. Stimwave's Freedom-4A and Freedom-8A include such signal delivery devices. Stimwave's product website states: "The stimulator has small metal electrodes near the tip that create an electrical field of energy when power is applied." (Ex. 17, Stimwave Freedom Stimulators website.) The images below from Stimwave's product website depict the signal delivery devices for the Freedom-4A and Freedom-8A. In these images, the electrodes are the shiny metal bands toward the left side of each device.

99. The claim refers to a signal delivery device "implantable in the patient's epidural space." Stimwave's signal delivery devices are implantable in the patient's epidural space. As explained in Stimwave's publication on its high frequency SCS study: "Subjects were implanted with two separate wireless stimulators positioned with the electrodes between the T8 and T11 vertebral levels regardless of the randomization assignment (Figure 2). All subjects were immediately implanted with a permanent wireless system using a Tuohy needle, placing the stimulator electrodes in the epidural space." (Ex. 18, Pain Medicine article at 2.)

100. Stimwave's product website also states that its signal delivery devices are implantable in the epidural space: "The Freedom SCS (Spinal Cord Stimulator) System is used to treat pain with placement of electrodes in the epidural space of the spinal column." (Ex. 61, http://stimwave.com/mobile/products/.)

2. Claim 45, Element [a]: "programming the signal generator to generate and deliver a therapy signal to the patient's spinal cord, via the implantable signal delivery device, wherein at least a portion of the therapy signal has"

101. The claim recites programming the signal generator to generate and deliver a therapy signal via the implantable signal delivery device. As discussed above, a clinical representative or physician may use a programmer to select certain specified signal parameters for the therapy.

102. Stimwave's clinical representatives program the signal generator in its SCS systems to deliver electrical signals to the patient's spinal cord via Stimwave's signal delivery devices. The programming is performed using Stimwave's WaveCrest programmer. (Ex. 19,

WaveCrest Programmer User Manual.) Stimwave's user manual for its WaveCrest programmer states that only its trained clinical representatives may use the programmer. (*Id*. at 3.)

103. The claim specifies "wherein at least a portion of the therapy signal" has certain parameters. I discuss those parameters and how Stimwave satisfies them in the sections below.

3. Claim 45, Element [b]: "a frequency in a frequency range of from about 1.5 kHz to about 50 kHz,"

104. The claim recites that at least a portion of the therapy signal has a frequency is in a frequency range from 1.5 kHz to 50 kHz. Stimwave's high frequency SCS therapy is at a frequency of 10 kHz.

105. In Stimwave's press release announcing the launch of its high frequency SCS, its CEO stated: "With the FDA clearance of 10,000 Hz, Stimwave U.S. patients now have an additional waveform to ensure maximum amount of ability to modify their programming to fit their individual pain management needs and decrease the effects of plasticity." (Ex. 9, April 1, 2019 Stimwave Press Release.)

106. Stimwave's study publication also states that its high frequency SCS therapy is at a frequency of 10 kHz. The title specifically refers to "Wireless High-Frequency Spinal Cord Stimulation (10 kHz)," and the abstract explains that it used the "wireless Freedom Spinal Cord Stimulator (WSCS) System for the treatment of chronic back and/or leg pain associated with failed back surgery syndrome (FBSS) refractory to standard medical treatment utilizing 10-kHz stimulation (high-frequency [HF])." (Ex. 18, Pain Medicine article at 1.)

107. Since the FDA approval of Stimwave's high frequency SCS, a number of public postings on LinkedIn indicate that Stimwave patients are receiving treatment with Stimwave's 10 kHz SCS therapy. (Exs. 12-14, LinkedIn posts.)

4. Claim 45, Element [c]: "a current amplitude in an amplitude range of from about 0.1 mA to about 6 mA,"

108. The claim recites that at least a portion of the therapy signal has a current amplitude in an amplitude from about 0.1 mA to about 6 mA.

109. It appears that Stimwave has not publicly disclosed the amplitude it uses for its high frequency SCS therapy.

110. Based on Stimwave's user manual for its WaveCrest programmer, it appears that the smallest step size by which the amplitude setting may be increased or decreased is 0.1 mA. (Ex. 19, WaveCrest Programmer User Manual at 27.) At an amplitude of zero, there would be no electrical signal. Therefore, the amplitude must be at least 0.1 mA.

111. Stimwave's study publication does disclose several other parameters of the high frequency SCS therapy it used, including positioning of the electrodes between the T8 and T11 vertebral levels, a frequency of 10 kHz, a pulse width of 30 microseconds, and paresthesia-free therapy. (Ex. 18, Pain Medicine article.) I understand from Dr. William Rosenberg, a physician with extensive experience treating patients with SCS, that for high frequency, paresthesia-free SCS therapy with the other parameters disclosed in Stimwave's study, the typical amplitude is below 6 mA.

112. Based on this information, it is more likely than not that Stimwave's high frequency SCS therapy uses an amplitude within the range specified by the claim. I understand that Nevro has requested that Stimwave provide information on the amplitudes it uses for its high frequency SCS therapy. I reserve the right to supplement my opinion if additional information becomes available.

5. Claim 45, Element [d]: "a pulse width between about 10 microseconds and about 333 microseconds, and"

113. The claim recites that at least a portion of the therapy signal has a pulse width between about 10 microseconds and about 333 microseconds.

114. Stimwave's study publication on its high frequency SCS therapy states that for 10 kHz SCS it used a pulse width of 30 microseconds. (Ex. 18, Pain Medicine article at 2 (referring to "HF stimulation (10 kHz and 30 μs)").) This pulse width falls within the range specified by the claim.

6. Claim 45, Element [e]: "at least partially reduces the patient's sensation of pain without generating paresthesia."

115. The claim recites that the therapy is programmed to at least partially reduce the patient's pain. Stimwave's press release announcing the launch of its high frequency SCS included a statement from its CEO, Laura Tyler Perryman: "With the FDA clearance of 10,000 Hz, Stimwave U.S. patients now have an additional waveform to ensure maximum amount of ability to modify their programming to fit their individual pain management needs and decrease the effects of plasticity." (Ex. 9, April 1, 2019 Stimwave Press Release.)

116. The Indications for Use for Stimwave's Freedom Spinal Cord Stimulator (SCS) System also describes its use in treating patients: "The Freedom Spinal Cord Stimulator (SCS) System is intended as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach for chronic, intractable pain of the trunk and/or lower limbs, including unilateral or bilateral pain." (Ex. 62, K182720 FDA Summary at Indications for Use.)

117. The claim recites that the therapy does not generate paresthesia. As I explained above, paresthesia refers to sensations such as tingling, numbness, or pins-and-needles that are used in traditional low frequency SCS to overlap with the patient's area of pain and mask the feeling of pain.

118. Stimwave's high frequency SCS does not generate paresthesia. Stimwave's high frequency study publication states that "tonic stimulation generates paresthesia whereas HF [high frequency] stimulation does not." (Ex. 18, Pain Medicine article at 2.)

119. In addition, Stimwave's "How It Works" webpage for its Freedom system states that "[t]he stimulation can feel like a tingling sensation or no sensation at all." (Ex. 60, http://stimwave.com/mobile/patients/how-it-works/.) "[N]o sensation at all" indicates that the therapy does not generate paresthesia.

E. '222 Patent Claim 48

'222 patent claim 48	48. The method of claim 45, wherein the frequency range is from about 3 kHz to about 20 kHz and the pulse width is between about 25 microseconds and about 166 microseconds.

120. Claim 48 depends from claim 45 and specifies the further limitation "wherein the frequency range is from about 3 kHz to about 20 kHz and the pulse width is between about 25 microseconds and about 166 microseconds."

121. As discussed above for claim 45, element [b], Stimwave's high frequency SCS therapy is at a frequency of 10 kHz. This falls within the range of 3 kHz to 20 kHz specified in claim 48. Based on Stimwave's public statements and Answer, it appears that Stimwave is also providing high frequency SCS therapy at other "frequencies up to 10,000 Hz." (Ex. 9, April 1, 2019 Stimwave Press Release; D.I. 8, ¶ 7.) To the extent that those frequencies are 3 kHz or higher, they also fall within the range specified in claim 48.

122. As discussed above for claim 45, element [d], Stimwave's study publication states that for 10 kHz SCS it used a pulse width of 30 microseconds, which falls within the pulse width range specified by claim 48. Therefore, Stimwave infringes claim 28.

XII. INDUCED INFRINGEMENT OF THE NEVRO PATENTS

123. As discussed above, it is my opinion that Stimwave directly infringes the patents. Stimwave's clinical representatives program its SCS systems to generate and deliver high frequency, paresthesia-free therapy that falls within the parameters of the asserted claims. Stimwave's user manual for its WaveCrest programmer states that only its trained clinical representatives may use the programmer. (Ex. 19, WaveCrest Programmer User Manual at 3.)

124. Even if it were the case that physicians (rather than Stimwave's clinical representatives) were conducting the steps of "delivering an electrical signal" or "programming the signal generator" of Stimwave's SCS systems, as I have described in the previous sections, Stimwave would still be inducing infringement by encouraging direct infringement of the asserted claims.

125. Stimwave is aware of Nevro's patents. For example, a February 2019 Stimwave presentation included excerpts from several news articles regarding Nevro's patent infringement suit against Boston Scientific. (Ex. 22, Feb. 2019 Presentation at 23.) The news articles note that the validity of Nevro's method claims directed to high frequency SCS was upheld by the court. (*Id.*) The articles also note that Boston Scientific was found not to infringe those claims because Boston Scientific "has *not* commercially launched a high-frequency SCS system in the United States" and "*doesn't* have a competing high-frequency SCS device on the U.S. market." (*Id.* (emphasis added).) Despite its awareness that Boston Scientific did *not* have a high frequency SCS system on the market, Stimwave concluded with the "Key Take-Away" that "Stimwave can have a high frequency product on the market." (*Id.*)

126. Stimwave's marketing and promotion of its 10 kHz SCS therapy is encouraging infringement of the asserted method claims. Its press release announcing its 10 kHz SCS therapy stated: "[t]he Freedom SCS system is currently available in the U.S. and worldwide, with

frequencies up to 10,000 Hz." (Ex. 9, April 1, 2019 Stimwave Press Release.) It touts Stimwave's therapy: "FDA cleared waveforms to 10,000 Hz available commercially in USA providing the most versatile opioid free neurostimulation options in the industry." (*Id.*)

127. Stimwave made similar announcements on LinkedIn, where it has over 4,000 followers. A Stimwave territory manager posted that "[w]e have a great product that just got better. We have every available waveform that is available in the United States in one system. No other company can say that." (Ex. 11, LinkedIn comment by Rickey Johnson.)

128. Stimwave has invited physicians to attend its presentation at the upcoming American Society of Interventional Pain Physicians Annual Meeting in Las Vegas (May 3-5, 2019) to promote its infringing therapy. The invitations ask physicians to "Hang 10k at the Stimwave Lunch Presentation" and to learn about "the benefits of a battery-free Spinal Cord Stimulator that is now FDA Cleared up to 10 kHz for effective pain relief." (Ex. 16, ASIPP Invitation.)

129. Physicians in the United States have already begun implanting Stimwave's infringing 10 kHz therapy and are offering such therapy to their patients. (Exs. 12-14, LinkedIn posts.) And Stimwave is actively encouraging physicians to do so. Stimwave recently posted on its LinkedIn page: "Congratulations to Dr. Chanë Price at the University of Miami Hospital on his first Stimwave SCS implant utilizing 10 kHz!" (Ex. 11, Price LinkedIn.)

XIII. CONCLUSION

130. My opinions above are based on available information to date. I reserve the right to supplement or amend my opinions in this report, and to respond to any opinions provided by Stimwave that I may disagree with.

I declare under penalty of perjury that the foregoing is true and correct. Executed on this 17th day of April, 2019 in Lincoln, Massachusetts.

Ben Pless

CERTIFICATE OF SERVICE

I hereby certify that on April 17, 2019, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on April 17, 2019, upon the following in the manner indicated:

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